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UNITED STATES RECEIVING OFFICE (RO/US)

Re	International Appln. No. PCT/EP2004/010538
U.S. Serial No.	10/574,183
U.S. Filing Date	March 30, 2006
Applicant	BADER et al., Rainer
International Filing Date	20 September 2004 (20.9.2004))
Title of Invention	ACETABULAR LINER
Agent's File	T55.12-0002

TRANSMITTAL

Mail Stop PCT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I HEREBY CERTIFY THAT THIS PAPER IS BEING
SENT BY U.S. MAIL, FIRST CLASS, TO THE
DIRECTOR OF THE U.S. PATENT AND TRADEMARK
OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-
1450, THIS

20 DAY OF June, 2006

PATENT ATTORNEY

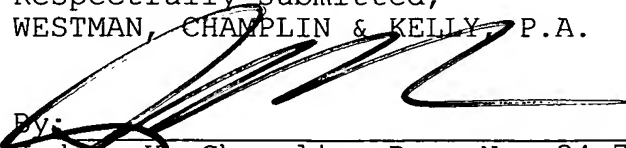
Dear Sir:

Enclosed for filing is the following paper in connection with
the above-identified patent application:

1. International Preliminary Report on Patentability
(IPRP)

The Director is authorized to charge any fee deficiency
required by this paper or credit any overpayment to Deposit
Account No. 23-1123. A duplicate copy of this communication is
enclosed.

Respectfully submitted,
WESTMAN, CHAMPLIN & KELLY, P.A.

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JKC:rev

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION
TREATY)

(PCT Rule 44bis.1(c))

To:

VOSSIUS & PARTNER
Siebertstrasse 4
81675 Munich
ALLEMAGNE

EINGEGANGEN

Vossius & Partner

19. April 2006

Date of mailing (*day/month/year*)
13 April 2006 (13.04.2006)

Applicant's or agent's file reference
H2134 PCT

Frist
bearb.:

IMPORTANT NOTICE

International application No.
PCT/EP2004/010538

International filing date (*day/month/year*)
20 September 2004 (20.09.2004)

Priority date (*day/month/year*)
30 September 2003 (30.09.2003)

Applicant

TECHNISCHE UNIVERSITÄT MÜNCHEN et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Agnes Wittmann-Regis

Facsimile No.+41 22 740 14 35

Facsimile No.+41 22 338 89 70

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference H2134 PCT	FOR FURTHER ACTION	See item 4 below
International application No. PCT/EP2004/010538	International filing date (<i>day/month/year</i>) 20 September 2004 (20.09.2004)	Priority date (<i>day/month/year</i>) 30 September 2003 (30.09.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant TECHNISCHE UNIVERSITÄT MÜNCHEN		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

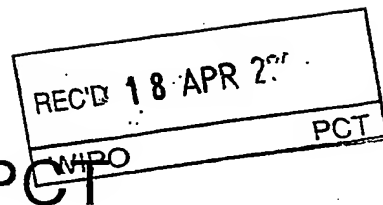
- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input checked="" type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

<p style="text-align: center;">The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. +41 22 740 14 35</p>	<p>Date of issuance of this report 03 April 2006 (03.04.2006)</p> <p>Authorized officer Agnes Wittmann-Regis</p> <p>Telephone No. +41 22 338 89 70</p>
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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY



To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/010538

International filing date (day/month/year)
20.09.2004

Priority date (day/month/year)
30.09.2003

International Patent Classification (IPC) or both national classification and IPC
A61F2/34

Applicant
TECHNISCHE UNIVERSITÄT MÜNCHEN

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Authorized Officer

Josten, S
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/010538

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/010538

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 2, 3

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 2, 3

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/010538

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☒ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☒ complied with
 - ☐ not complied with for the following reasons:
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1, 4-15

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	4,7,8,10,14
	No: Claims	1,5,6,9,11,12,13,15
Inventive step (IS)	Yes: Claims	
	No: Claims	1, 4-15
Industrial applicability (IA)	Yes: Claims	1, 4-15
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item IV.

1. The present application comprises the following three inventions:
 - a) the acetabular liner according to independent claim 1, followed by dependent claims 4 to 12 and 15, and the method of manufacturing an implant according to independent claim 13, followed by dependent claim 14,
 - b) the acetabular liner according to independent claim 2, followed by dependent claims 4 to 12 and 15, and the method of manufacturing an implant according to independent claim 13, followed by dependent claim 14, and
 - c) the acetabular liner according to independent claim 3, followed by dependent claims 4 to 12 and 15, and the method of manufacturing an implant according to independent claim 13, followed by dependent claim 14.

The above-mentioned three inventions of the present application are not so linked that they form a single general inventive concept. The single general inventive concept linking several inventions according to different independent claims can be defined by the common features of these claims. In the present case, the features in common between independent claims 1, 2 and 3 are the following:

An acetabular liner for receiving a femoral head fixed on a stem component comprising:

an outer surface;

an inner surface being concave and forming a cavity adapted to receive the femoral head; and

a rim surface located circumferentially along the top edge of the liner and joining upper edges of the inner and outer surfaces, the rim surface having at least one elevated portion and at least one non-elevated portion.

These features, however, are not novel since they are known from each of the documents cited in the Search Report.

As to D1 (=US-B-6290727); see Figures 1 to 4; see the elevated portion at both sides of the apex 18; see the non-elevated portion 52.

As to D2 (=US-A-2003/0050703; see Figure 2; see the elevated portions between the

two cut aways 36; see the non-elevated portions 36.

As to D3 (=US-A-4950299); see Figure 2; see the elevated portions at reference numeral 28; see the non-elevated portions at reference numerals 24.

As to D4 (=FR-A-2749162); see Figure 4; see the elevated portion 202; see the non-elevated portion formed by the rest of the rim surface.

Consequently, there is no single general inventive concept linking present independent claims 1, 2 and 3 and the application, therefore, does not meet the requirements of Article 13.1 PCT.

Re Item V.

2. The following documents have been cited in the Search Report:

D1: US-B1-6 290 727 (KELLER ARNOLD ET AL) 18 September 2001 (2001-09-18)

D2: US 2003/050703 A1 (BURROUGHS BRIAN R ET AL) 13 March 2003 (2003-03-13)

D3: US-A-4 950 299 (NOILES DOUGLAS G) 21 August 1990 (1990-08-21)

D4: FR-A-2 749 162 (FAUVY ALAIN) 5 December 1997 (1997-12-05)

3. An acetabular liner according to the features of claim 1 is known from each of the documents cited in the Search Report.

D1 discloses a concave portion of the transitional area at least at one side of the lowest part of the cut-off edge 2 in Figure 2.

D2 discloses two concave portions in Figure 2.

D3 discloses four concave portions at both sides of the two lowest parts of the rim in Figure 2.

D4 discloses a concave portion of the transitional area in Figure 4 (compare Figure 4 of the present application with Figure 4 of **D4**).

Thus, claim 1 does not meet the requirements of Article 32(2) PCT.

4. The features of claims 5, 6, 11, 12, 13 and 15 are known from **D2** and the features of claim 9 are known from **D4**. Thus, claims 5, 6, 9, 11, 12, 13, and 15 do not meet the requirements of Article 33(2) PCT.
5. The features of claim 14 cannot be seen as involving an inventive step since the use of milling cutters is customary with the manufacturing of implants and comes within the scope of the customary practice followed by persons skilled in the art. Claim 14, therefore, does not meet the requirements of Article 33(3) PCT.
6. Claims 7 and 8 each attempt to define a feature (i.e. the bevelled surface) by a result to be achieved (claim 7: such that a femoral neck first contacts an inner edge of the bevelled surface and then contacts the entire bevelled surface; claim 8: so formed that a snap fit between the femoral head and the liner is provided over the entire circumference of the cavity of the liner). Thus, Claims 7 and 8 are drafted in functional terms, i.e. they indicate the result to be obtained without defining the means necessary for achieving the desired result. Such a formulation is not allowable since the man skilled in the art would have to employ an inventive step in order to find a solution to the problem posed. The claims should rather specify the technical features of the bevelled surface which are essential for leading to the result. Thus, claims 7 and 8 do not meet the requirements of Article 6 PCT..

Claims 10 and 11 are not clear (Article 6 PCT), since these claims do not only define an acetabular liner per se but its relationship to the neck of a stem component which is not part of the claimed acetabular liner. For reasons of clarity, claims 10 and 11 should be made dependent upon claim 15 which relates to a combination of a liner, a cup and a femoral component.

As far as the dependent claims 4, 7, 8 and 10 can be understood, these claims do not appear to involve an inventive step thus not meeting the requirements of Article 33(3) PCT.